



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Subhashis Banerjee *et al.*

Serial No.: 10/623039

Filed: July 18, 2003

For: *Treatment of Spondyloarthropathies Using TNF $\alpha$  Inhibitors*

Attorney Docket No.: BPI-188

Group Art Unit: 3652

Examiner: Not Yet Assigned

MS Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
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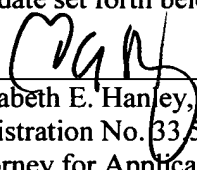
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By:

  
Elizabeth E. Hanley, Esq.  
Registration No. 33,505  
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:


Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form SB/08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se*

as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

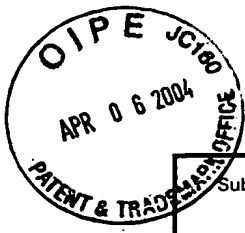
Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

  
\_\_\_\_\_  
Elizabeth A. Hanley, Esq.  
Registration No. 33,505  
Attorney for Applicants

28 State Street  
Boston, MA 02109  
(617) 227-7400

Date: April 2, 2004

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	2	Attorney Docket Number	BPI-188
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**Complete if Known**

Application Number	10/623039
Filing Date	July 18, 2003
First Named Inventor	Subhashis Banerjee
Art Unit	3652
Examiner Name	Not Yet Assigned
Attorney Docket Number	BPI-188

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	6,090,382	07-18-2000	Salfed <i>et al.</i>	
	A2	6,509,015 B1	01-21-2003	Salfed <i>et al.</i>	
	A3	US 2003/0219438 A1	11-27-2003	Salfed <i>et al.</i>	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	A4	WO 97/29131 A1	08-17-1997	BASF Aktiengesellschaft		

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A5	Asli B, <i>et al.</i> Inhibition of tumor necrosis factor alpha and ankylosing spondylitis. N Engl J Med. 2003 Jan 23;348(4):359-61	
	A6	Brandt J, <i>et al.</i> Successful treatment of active ankylosing spondylitis with the anti-tumor necrosis factor alpha monoclonal antibody infliximab. Arthritis Rheum. 2000 Jun;43(6):1346-52.	
	A7	Braun J, <i>et al.</i> Therapy of ankylosing spondylitis and other spondyloarthritides: established medical treatment, anti-TNF-alpha therapy and other novel approaches. Arthritis Res. 2002;4(5):307-21.	
	A8	Braun J, <i>et al.</i> Anti-tumour necrosis factor alpha therapy for ankylosing spondylitis: international experience. Ann Rheum Dis. 2002 Dec;61 Suppl 3:iii51-iii60.	
	A9	Braun J, <i>et al.</i> Treatment of active ankylosing spondylitis with infliximab: a randomized controlled multicentre trial. Lancet. 2002 Apr 6;359(9313):1187-93	
	A10	Braun J, <i>et al.</i> New treatment options in spondyloarthropathies: increasing evidence for significant efficacy of anti-tumor necrosis factor therapy. Curr Opin Rheumatol. 2001 Jul;13(4):245-9.	
	A11	Braun J, <i>et al.</i> Anti-TNFalpha: a new dimension in the pharmacotherapy of the spondyloarthropathies!? Ann Rheum Dis. 2000 Jun;59(6):404-7.	
	A12	Braun J, <i>et al.</i> International ASAS consensus statement for the use of anti-tumour necrosis factor agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2003 Sep;62(9):817-24.	
	A13	Brandt J, <i>et al.</i> Successful short term treatment of severe undifferentiated spondyloarthritis with the anti-tumor necrosis factor-alpha monoclonal antibody infliximab. J Rheumatol. 2002 Jan;29(1):118-22.	
	A14	Braun J, <i>et al.</i> Novel approaches in the treatment of ankylosing spondylitis and other spondyloarthritides. Expert Opin Investig Drugs. 2003 Jul;12(7):1097-109.	
	A15	Braun J, <i>et al.</i> Biologic therapies in the spondyloarthritis: new opportunities, new challenges. Curr Opin Rheumatol. 2003 Jul;15(4):394-407.	

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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	B1	Breban M, <i>et al.</i> Efficacy of infliximab in refractory ankylosing spondylitis: results of a six-month open-label study. <i>Rheumatology (Oxford)</i> . 2002 Nov;41(11):1280-5. Efficacy of infliximab in refractory ankylosing spondylitis: results of a six-month open-label study. <i>Rheumatology (Oxford)</i> . 2002 Nov;41(11):1280-5.		
	B2	Boeger CA, <i>et al.</i> Treatment of ankylosing spondylitis with infliximab. <i>Ann Rheum Dis</i> . 2001 Dec;60(12):1159-60.		
	B3	Dayer JM, Krane SM. Anti-TNF-alpha therapy for ankylosing spondylitis—a specific or nonspecific treatment? <i>N Engl J Med</i> . 2002 May 2;346(18):1399-400		
	B4	Dernis E, <i>et al.</i> Infliximab in spondylarthropathy—influence on bone density. <i>Clin Exp Rheumatol</i> . 2002 Nov-Dec;20(6 Suppl 28):S185-6.		
	B5	Gorman JD, <i>et al.</i> Treatment of ankylosing spondylitis by inhibition of tumor necrosis factor alpha. <i>N Engl J Med</i> . 2002 May 2;346(18):1349-56.		
	B6	Horneff G, <i>et al.</i> TNF-alpha antagonists for the treatment of juvenile-onset spondyloarthritides. <i>Clin Exp Rheumatol</i> . 2002 Nov-Dec;20(6 Suppl 28):S137-42.		
	B7	Kaiser MJ, <i>et al.</i> Efficacy of infliximab (Remicade) in the treatment of spondyloarthropathies two case reports. <i>Joint Bone Spine</i> . 2001 Dec;68(6):525-7.		
	B8	Maksymowych WP, <i>et al.</i> Canadian Rheumatology Association Consensus on the use of anti-tumor necrosis factor-alpha directed therapies in the treatment of spondyloarthritis. <i>J Rheumatol</i> . 2003 Jun;30(6):1356-63.		
	B9	Marzo-Ortega H, <i>et al.</i> Inhibition of tumor necrosis factor alpha and ankylosing spondylitis. <i>N Engl J Med</i> . 2003 Jan 23;348(4):359-60; author reply 360-61.		
	B10	Pham T, <i>et al.</i> Initiation of biological agents in patients with ankylosing spondylitis: results of a Delphi study by the ASAS Group. <i>Ann Rheum Dis</i> . 2003 Sep;62(9):812-6.		
	B11	Reimold AM. New indications for treatment of chronic inflammation by TNF-alpha blockade. <i>Am J Med Sci</i> . 2003 Feb;325(2):75-92.		
	B12	Schnarr S, <i>et al.</i> Anti-tumour necrosis factor (TNF)-alpha therapy in undifferentiated spondyloarthropathy. <i>Clin Exp Rheumatol</i> . 2002 Nov-Dec;20(6 Suppl 28):S126-9.		
	B13	Sieper J, <i>et al.</i> New treatment options in ankylosing spondylitis: a role for anti-TNFalpha therapy. <i>Ann Rheum Dis</i> . 2001 Nov;60 Suppl 3:iii58-61.		
	B14	Stokes DG, <i>et al.</i> Potential of tumor necrosis factor neutralization strategies in Rheumatologic disorders other than rheumatoid arthritis. <i>Semin Arthritis Rheum</i> . 2003 Aug;33(1):1-18.		
	B15	Stone M, <i>et al.</i> Clinical and imaging correlates of response to treatment with infliximab in patients with ankylosing spondylitis. <i>J Rheumatol</i> . 2001 Jul;28(7):1605-14.		
	B16	Van den Bosch F, <i>et al.</i> Crohn's disease associated with spondyloarthropathy: effect of TNF-alpha blockade with infliximab on articular symptoms. <i>Lancet</i> . 2000 Nov 25;356(9244):1821-2.		
	B17	Zou JX, <i>et al.</i> Immunological basis for the use of TNF-alpha-blocking agents in ankylosing spondylitis and immunological changes during treatment. <i>Clin Exp Rheumatol</i> . 2002 Nov-Dec;20(6 Suppl 28):S34-7.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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